Department of Health Professions

Virginia Board of Pharmacy
Law Update

VPhA Annual Convention
August 2, 2011

Caroline Juran, Executive Director

Current Board Members

- Gill B. Abernathy, Chairman
- David C. Kozera, Vice-Chairman
- Jody H. Allen
- John O. Beckner
- Gerard Dabney
- Robert M. Rhodes
- Leo H. Ross
- Ellen B. Shinaberry
- Pratt P. Stelly
- Brandon K. Yi

Program Objectives

- Briefly review new laws which may impact the profession of Pharmacy
- Review new regulations
- Review legislative proposal for 2012 General Assembly session
- Review proposed regulations
- Provide status update of new routine inspection process
- PMP Update

New Laws

§54.1-3434.03 Continuous Quality Improvement Program

- Pharmacies must implement a CQI program, according to Board regulations
- Provides a systematic, ongoing process of analysis of dispensing errors
- Uses findings to formulate an appropriate response
- Develops or improves pharmacy systems and workflow processes to prevent or reduce future errors

§54.1-3434.03 Continuous Quality Improvement Program

- Pharmacies actively reporting to a patient safety organization that has as its primary mission CQI under the Patient Safety and Quality Improvement Act of 2005 shall be deemed in compliance with this section.

§54.1-3434.03 Continuous Quality Improvement Program

- NOIRA published
- Comment period open until August 31, 2011
- View information at http://www.townhall.virginia.gov/L/publiclogin.cfm
- 2nd meeting of taskforce on August 25th
- Board may adopt proposed regulations at September full board meeting
- Once published, will have another opportunity to submit comment.

§54.1-3434.03 Continuous Quality Improvement Program

- Subjects that may be included in regulations:
  - Definition of “dispensing error”
  - Requirement to report dispensing error to pharmacist on-duty
  - Requirement to initiate documentation of error
  - Requirement to analyze error, assess cause recommendations for changes
  - Allowance to rid of documentation after Q/A performed
  - Requirement to maintain record indicating dates when Q/A performed and confirmation that action was taken

§54.1-3434.03 Continuous Quality Improvement Program

- Subjects that may be included in regulations:
  - Requirement that patient safety organization be credentialed by Agency for Healthcare Research Quality
  - Definition for “actively reports” – may mean reporting all dispensing errors to PSO weekly

§ 32.1-127.1:03 Health records privacy

- Prescriber or dispenser may disclose information from the PMP and contained in a patient's health care record to another health care provider when such disclosure is related to the care or treatment of the patient
- Prescriber or dispenser may disclose information from the PMP to another prescriber or dispenser who has prescribed or dispensed a controlled substance to a recipient.

§54.1-3420.1 Proof of identity

- Certain duties may be undertaken by the agent of the pharmacist and reduces retention time of records.
- Person picking up Schedule II is known to the pharmacist or his agent, pharmacist or his agent is not required to obtain ID.
- Person picking up Schedule II prescription is patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID.

§54.1-3420.1 Proof of identity

- Anyone other than patient for whom the prescription is written seeks to take delivery of the drug, and the pharmacist or his agent does not know the person, then pharmacist or his agent must either make a photocopy or an electronic copy of such person's ID *or* record the full name and address of such person. The pharmacist must keep the record or copy of ID for at least one month.

§54.1-3420.1 Proof of identity

- ID = driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address
- Guidance document 110-11 amended to conform to changes.

Amended Regulation

18VAC110-20-490 Automated dispensing devices

- Petition for rulemaking received to rid of requirement for nurse to sign delivery record when delivery drugs in hospital to be placed in automated dispensing devices
- Effective March 17, 2011

Legislative Proposal

Legislative Proposal- Scheduling tramadol and carisoprodol as CIV

- June 2010-Board reviewed petition for rulemaking to schedule tramadol as a Schedule IV in regulation
- Board generally agreed tramadol and carisoprodol were known drugs of abuse and should be scheduled
- Determined would be best to follow precedence of scheduling in legislation instead of regulation

Legislative Proposal- Scheduling tramadol and carisoprodol as CIV

- Was not selected to be included in Governor's packet for 2011 General Assembly Session
- Board voted to approve proposal again
- Governor may or may not choose to include in packet for 2012 General Assembly Session

Proposed Regulations

On-hold Prescriptions

- September 2010 - Board reviewed a petition for rulemaking to allow prescriptions to be filed chronologically by date of initial dispensing or initial entry into the computer
- Current rule potentially requires on-hold prescription to be moved by date of initial dispensing
- Board denied petition, but agreed to research issue to gather more information

On-hold Prescriptions

- Surveyed states; only 2 have rules but concerns exist
  - By not requiring data entry of on-hold prescriptions, prescriptions can be lost or stolen
  - No pharmacist verification of data entry may lead to dispensing errors
  - Current filing requirement may be burdensome
- NOIRA adopted and published

On-hold Prescriptions

- Proposed regulations require:
  - Filing of prescription by date of initial dispensing or date of initial entry into automated data processing system
  - Documentation that pharmacist verified accuracy of data entry
  - Data entry of on-hold prescription must occur

On-hold Prescriptions

- Proposed regulations require:
  - Pharmacist dispensing on-hold prescription must perform prospective drug review
  - data entry must be deleted if patient requests on-hold prescription back prior to dispensing
- Board may adopt proposed regulations at September full board meeting
- Another public comment period will begin once receive authorization to publish

Petition for Rulemaking

18VAC110-20-490 Automated dispensing devices

- Petition received May 27, 2011 to amend requirements for monthly inspection of devices in hospitals
- Argues current software can perform or eliminate need for some manual auditing processes
- Public comment ended July 11th
- Board to consider at September meeting whether to initiate regulatory action

Board Inspection Process

Routine Inspection Process

- At the conclusion of a routine inspection:
  - inspection summary will be provided;
  - expedited prehearing consent order imposing a monetary penalty may be provided.
- Monetary penalties derived from guidance document 110-9. http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm

Routine Inspection Process

Two options for resolving inspection with deficiencies:

1. Within 30 days of receiving the notice, submit to the Board office:
   - signed prehearing consent order;
   - documentation that all deficiencies have been corrected;
   - payment for the monetary penalty.
2. Request in writing an informal conference for hearing the matter.
   - could result in disciplinary sanctions in addition to the monetary penalty listed on the prehearing consent order.

Routine Inspection Process

- Community pharmacies – have been live with this process since July 2010
- All of other pharmacies - went live in July 2011

Question

Does the Board benefit financially from the collection of monetary penalties?

Question

- No.
- Monetary penalties do NOT remain with the Board.
- All monetary penalties must be transferred by law to the Virginia Literary Fund.

Frequently Cited Deficiencies

Perpetual inventory (major 15)

- A perpetual inventory of all Schedule II drugs received and dispensed shall be performed with reconciliation at least _____.

- How often?

Perpetual inventory

- Monthly, per regulation.
- Threshold in guidance document 110-9 for citing deficiency – allows perpetual inventory to be performed as early as seven days prior to the applicable calendar month and as late as seven days after the applicable calendar month.

Perpetual inventory

- Inspector is requesting proof that a perpetual inventory was taken in November 2010, December 2010, and January 2011. If the pharmacy's perpetual inventories were taken on these dates, is the pharmacy in compliance?
  - November 10, 2010
  - November 30, 2010
  - February 4, 2011

Perpetual inventory

- Yes.
  - November 10, 2010 (November inventory)
  - November 30, 2010 (December inventory)
  - February 4, 2011 (January inventory)

Perpetual inventory

- If a pharmacy has not dispensed a particular Schedule II drug that month, must it be inventoried during the monthly perpetual inventory?

Perpetual inventory

- Yes.
- All Schedule II drugs must be inventoried, including any expired drugs.

Biennial Inventory

- **biennial inventory** (major 13 and minor 12) taken on any date within two years of the previous biennial inventory

- Must include expired drugs.

Biennial Inventory

- Must you physically count all drugs during the biennial inventory or may you estimate the count?

Biennial Inventory

- You may estimate in accordance with guidance document 110-16.

Guidance document 110-16

- physically count all drugs in Schedules II-V when a theft or loss of drug has occurred;
- otherwise may perform the inventory in a manner consistent with federal allowances which require a physical count of drugs in Schedule II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules; but,
- nothing would prevent a person from choosing to physically count all drugs in Schedules II-V.

Incoming PIC Inventory

- When must the incoming PIC inventory be taken?

Incoming PIC Inventory

- As of the date the individual becomes PIC and prior to opening for business on that date.
- Must include expired drugs.

Frequently Cited Deficiencies

- **Pharmacist not checking** and documenting repackaging, compounding, or bulk packaging (major 20)
  - Must be able to demonstrate which pharmacist verified accuracy of every dispensed drug

Frequently Cited Deficiencies

- If pharmacy is not open 24/7, **security system** be capable of sending an alarm signal to the monitoring entity when breached if the primary communication line is not operational (major 9).

Frequently Cited Deficiencies

- If **emergency key** or other means of unlocking the prescription department and the alarm access code maintained (minor 8):
  - Place sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy.
  - In lieu of the pharmacist's signature across a seal, the executive director for the Board may approve other methods of securing the emergency access. When approved, strongly recommended to maintain letter of approval.

Frequently Cited Deficiencies

- Pharmacy's **refrigerator or freezer** is not monitored by a thermometer or the temperature varies from that required by regulation (major 8 and minor 5).

Preparing for a Routine Inspection

- Perform a self-inspection using applicable sections of inspection report found at http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm
- Get organized by creating a folder containing locations of information inspector will need to review.

Tips – Create a Folder Containing:

- Inventories (biennial and PIC changes) performed within the last 2 years;
- Location of invoices
  - Schedule II----2 years
  - Schedule III-V----2 years
  - Schedule VI----since September 2009

Tips – Create a Folder Containing (cont.):

- Location of dispensing data verification for previous 2 years
  - Printout
  - Separate File
  - Bound Log Book

Tips – Create a Folder Containing (cont.):

- Location of records of destruction for previous 2 years;
- Location of repackaging records for previous 1 year;
- Location of applicable policies and procedure manuals;

Tips – Create a Folder Containing (cont.):

- List of pharmacists and pharmacy technicians employed, both full time and part-time;
- If have pharmacy technician trainee:
  - Documentation indicating date enrolled in Board-approved pharmacy technician training program, progress, and completion date

Department of Health Professions

- Board of Pharmacy website:
  www.dhp.virginia.gov/pharmacy

- Email : pharmbd@dhp.virginia.gov

Department of Health Professions

VIRGINIA'S PRESCRIPTION MONITORING PROGRAM

Program Update

INTEROPERABILITY

- Early to mid-August will go in production
- Initially share with Ohio and Indiana
- West Virginia will be added shortly
- As many as 20+ states anticipated to be available by the end of 2011.

NEW SOFTWARE UPGRADE

- Go Live—October 3, 2011
- Password reset without having to call PMP
- Easier to find reports
- Work with several types of browsers (IE and Firefox)

NEW REPORTING REQUIREMENTS

- Effective October 1, 2011
  - Within 7 days of dispensing
  - Date Written
  - New or Refill
  - Number of Refills Ordered
  - DEA Number of Dispenser
- ASAP Version 4.1
  - Enhanced error correction capabilities
  - Zero report capabilities for those using FTPS for file upload
  - Most current version—required for grant eligibility

PROGRAM CONTACT INFORMATION

- Program Phone #: 804-367-4566
- Fax 804-527-4470
- Email- pmp@dhp.virginia.gov
- www.dhp.virginia.gov/dhp_programs/pmp/default.asp

Questions??